TESTIMONY OF STERILMED, INC.
BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM
SEPTEMBER 26, 2006

I. Introduction

My name is Dennis J. Toussaint and I have been Director of Regulatory Affairs at SterilMed, Inc. (SterilMed) since November 21, 2005. Founded in 1997, SterilMed is a leading provider of reprocessing and repair services designed to help hospitals and other health care organizations generate substantial cost savings through better utilization of medical devices. As a medical device reprocessor, SterilMed cleans, tests, packages and sterilizes previously utilized devices that were originally labeled for single use only. During a time of rapidly rising health care costs, SterilMed helps its hospital partners free up critical financial resources that can then be devoted to improving their delivery of medical services, while maintaining the highest possible quality of patient care.

I have been employed in the regulatory field for approximately 18 years, working for large and small medical device manufacturers, as well as a number of start-up companies developing novel medical technologies. My educational background includes a Bachelor of Science degree in Pharmacy Practice and a Master of Science degree in Hospital Pharmacy Administration and Clinical Pharmacy Practice.

At SterilMed, I am responsible for assuring the company's compliance with all reprocessing-related federal, state and local regulations. In particular, it is my responsibility to ensure compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) and the medical device-related regulations of the Food and Drug Administration (FDA). I also assure compliance with ISO 13485, an international voluntary standard that is an FDA-recognized consensus standard for quality management systems, written to apply directly to device manufacturers.

My responsibilities include determining regulatory pathways for products that SterilMed proposes to reprocess and determining what data and information are required to be submitted to relevant regulatory authorities. I also participate in meetings of product development teams to provide input relating to compliance with federal regulations and, in particular, validation testing that must be performed to ensure a safe and effective product.

SterilMed currently has 328 full-time employees and 40 part-time employees. Our superior management team is comprised of extremely qualified and competent personnel recruited from original equipment manufacturers (OEMs), including Johnson & Johnson, US Surgical, Owens & Minor and Kimberly-Clark. SterilMed has an extensive in-house development team consisting of nurses, surgical technicians, and biomedical engineers. In addition, SterilMed employs approximately 50 surgical technicians as independent contractors and approximately 75 independent sales representatives.

SterilMed provides reprocessing services to approximately 1,400 health care facilities throughout the U.S. and Canada, including major hospital networks and group

purchasing organizations such as Amerinet, Broadlane, Consorta, Magnet, Premier, Shared Services Health care Inc., MedAssets, Ascension and Trinity.

SterilMed reprocesses approximately 2 million devices per year and has reprocessed over 7 million devices since its inception. Most of these devices are surgical and general hospital use devices. SterilMed does not reprocess devices regulated by FDA as Class III ("high risk") devices.

SterilMed currently saves hospitals over $40 million per year in device expenditures. Since inception we believe we have saved hospitals over $120 million dollars. Moreover, last year, SterilMed prevented approximately 585 tons of waste from entering landfills. Since the inception of the company, over 1,750 tons of waste have been diverted from the waste stream. SterilMed is aligned with Hospitals for a Healthy Environment, an organization that educates health care professionals and assists hospitals with their pollution prevention efforts.

II. History of Reprocessing in the United States

The emergence of reprocessing in the United States is rooted in the meaning of the "single use" label itself. Contrary to what one might think, the "single use" label is not an FDA requirement. In fact, FDA does not require any device to carry a single use label. Instead, "single use" is a designation that the OEM chooses, and that choice is sometimes made in an effort to sell more devices, not for patient safety reasons. The truth is that a manufacturer could label an operating table as being intended for "single use," if the OEM believed that it could persuade a hospital to throw the table out after one use.

It is the fact that the OEM, rather than FDA, makes the decision about whether a device will be labeled for single use, that really accounts for the emergence of the reprocessing of devices labeled for single use. Approximately two decades ago, some OEMs began to change the label on certain medical devices from "reusable" to "single use" — in some cases without any significant structural changes in the devices that would preclude safe reuse.[1]

With this change in labeling, it became evident to many hospitals that the "single use" label does not necessarily mean "single use," and that certain devices designated by the original manufacturer as "single use" can, in fact, be safely reprocessed. Hospital skepticism of the single use label was noted in a 2000 study of reprocessing conducted by

[1] For example, in a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products explained that, although it was changing the label on its intracardiac electrodes from "reusable" to "single use," "our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past." Letter from Product Manager, USCI Cardiology & Radiology Products (July 24, 1980).

the Government Accountability Office (GAO).[2] The GAO found that health care personnel "distrust the single-use label for some devices because [among other things] . . . . FDA cannot require manufacturers to support the designation of a device as single-use," and because "they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable."[3] Further evidence that the "single use" label does not always mean "single use" is the fact that some OEMs offer reprocessing services to hospitals for the OEM's own "single use" devices.[4] In fact, some OEMs partner with third-party reprocessors to reprocess devices that the OEM itself has labeled as "single use."[5]

The reality of the single use label has led to a predictable result. Reprocessing of devices originally labeled for single use has been standard practice in the nation's hospitals for over two decades. As a practical matter, hospitals simply cannot afford to throw out devices that can be safely reprocessed. These are dollars that are better spent on purchasing new medical technology and preserving nursing staff. The savings generated by reprocessing are significant, because a reprocessed device costs approximately one-half the price of an original device. The GAO study mentioned above found that for one device alone — a product called the electrophysiology catheter — individual hospitals are saving between $200,000 and $1 million annually as a result of reprocessing.[6]

As the reprocessing industry has grown, so, too, has the strident opposition to the practice from OEMs, who see reprocessing as an increasing economic threat. The threat is two-fold. First, reprocessed devices are, on average, half the cost of original devices.

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2 United States General Accounting Office Report entitled *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* 3 (June 2000) [hereinafter *GAO Report*].

3 *Id.*

4 *See* "OEM Moves Into Reprocessing," Medical Design Technology, March 1, 2006, explaining, "Orthopedic firm Synthes is offering hospitals the option to reprocess used external fixation devices as part of a new reprocessing program. The U.S. division of the Swiss firm is reprocessing over a dozen of its fixation devices, including single use devices such as its 'combination clamp' and 'tube to tube clamps,' according to a marketing document." *See also, Synthes, External Fixation Reprocessing Program*, Corporate Marketing Material, Synthes USA 2004. *See also*, FDA 510(k) clearance K033158, "Synthes (USA) Synthes Reprocessed External Fixation Devices," cleared by FDA on November 5, 2003.

5 *See* "Nellcor and Alliance Medical Announce First-of-its-Kind Co-Marketing," Infection Control Today (April 8, 2003).

6 GAO Report, *supra* note 2, at 19.

Therefore, many hospitals choose to use reprocessed devices rather than purchase new ones. This means lower sales for original device manufacturers. Second, the very existence of reprocessing has resulted in a decrease in the price of certain new devices.[7] Lower prices typically mean lower profits.

Beginning in the late 1990s, therefore, certain OEMs began to put intense pressure on federal and state government to ban or restrict reprocessing. As their rationale, these OEMs have argued (contrary to all available evidence) that reprocessing puts the public health at risk. And the pressure that OEMs have placed on legislators and regulators has resulted in a period of intense scrutiny of reprocessing, which continues today. Faced with the economic threat posed by reprocessing, these OEMs have engaged in a concerted effort to achieve the enactment of legislation and regulation (on the federal and state levels) that would effectively eliminate the third-party reprocessing industry.[8] *See* Exhibit A. Although the regulatory scrutiny of the industry has, in fact, been intensified in the last six years, and regulatory requirements have grown significantly more stringent, the industry has nevertheless consistently been able to meet the new regulatory requirements and, indeed, has flourished.

SterilMed hopes that its testimony today will make clear that the third-party reprocessing industry in the United States is safe, that it is highly regulated — more stringently regulated than the original equipment industry — and that it is providing a valuable service to this country's hospitals, a service that helps hospitals survive and thrive in a time of severe cost containment pressures. Additional regulation at either the federal or state level is not only unnecessary but also, to the extent it would limit the ability of hospitals to use reprocessed devices, would do a disservice to America's hospitals and patients.

III. FDA Regulation of Reprocessed Devices

In order to evaluate the adequacy of the federal regulatory scheme governing reprocessed devices, it is necessary to understand how the FDA regulatory framework governing reprocessing has evolved, and how it is that, today, reprocessors are more stringently regulated than original device manufacturers.

A. Pre-2000 Regulatory Scheme

Prior to August 2000, FDA regulated third-party reprocessors in the same way that it regulates OEMs, with the only exception being that reprocessors were not subject to premarket review requirements. As medical device "manufacturers," however,

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[7] In studying this issue, the GAO found that, because of the competitive alternative presented by reprocessing, manufacturers have lowered their prices in exchange for a hospital's commitment not to reprocess. *Id*.

[8] *See* Exhibit A.

reprocessors *were* subject to FDA's establishment registration and medical device listing requirements,[9] medical device reporting requirements,[10] reports of corrections and removal requirements,[11] quality system regulation ("QSR") requirements,[12] and labeling requirements.[13] Reprocessing that took place inside hospitals, however, was not regulated by FDA as a device manufacturing activity.

B. August 2000 Guidance Document

On August 14, 2000, FDA issued a document entitled, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." In that document, FDA announced a significant increase in its regulatory oversight of reprocessing. First, third-party reprocessors became subject to premarket review requirements in addition to all of the other post-market manufacturer controls with which they already had to comply. As a result, today, reprocessors, like OEMs, are required to submit premarket notifications (510(k)) for the Class I and Class II devices that they reprocess, unless those devices are by regulation exempt from this requirement. The elements of a 510(k) submission for a reprocessed device include the following:

- information on the company submitting the 510(k);
- a summary of the information presented in the submission;
- a complete description of the device that is the subject of the submission;
- all pre-production validation data related to cleaning, testing, packaging, and sterilization, including mechanical testing data, electrical testing data, cleaning validation data, sterilization validations, and packaging validations;
- an analysis of the risks related to reprocessing the device (identification of the risks; determination of the likelihood of each risk occurring; and steps taken by the reprocessor to mitigate each risk);

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9 21 U.S.C. § 360; 21 C.F.R. Part 807, subpart B.

10 21 U.S.C. § 360i(a); 21 C.F.R. Part 803.

11 21 U.S.C. § 360i(f); 21 C.F.R. Part 806.

12 21 U.S.C. § 360j(f); 21 C.F.R. Part 820.

13 21 U.S.C. §352; 21 C.F.R. Part 801.

- biocompatibility analyses (laboratory-based determinations of the potential that the reprocessing method, residuals, etc. may cause a cellular reaction);
- labeling, including the product labels and instructions for use;
- a comprehensive comparison of the original and reprocessed devices; and
- a certification that all information in the submission is complete, truthful and accurate.

A 510(k) submission for a reprocessed device may contain thousands of pages of information, cost between $50,000 and $250,000 to develop, and may take more than a year to complete.

The second significant change that came about in 2000 was that FDA began to regulate hospitals that perform their own reprocessing as device manufacturers and subjected them to the full range of FDA device manufacturer requirements. Therefore, the "bottom line" was that reprocessing of single use devices — whether performed by a commercial firm or a hospital — would be viewed by FDA as a device manufacturing activity and would be subject to the same regulatory requirements as original equipment manufacturing.

The reprocessing industry did not fade away as a result of the new premarket submission requirements. Rather, the industry was able to comply with the new requirements, and many hospitals that had previously reprocessed their devices in-house began to send them to third-party reprocessors, rather than trying to comply with FDA's device manufacturing requirements.

While FDA's 2000 initiatives "leveled the playing field," by requiring reprocessors and OEMs to comply with the same regulatory requirements, subsequent legislation imposed new regulatory obligations on reprocessors. As a result, as described below, reprocessors are now more stringently regulated than OEMs.

C. The Medical Device User Fee and Modernization Act of 2002

In 2002, the Medical Device User Fee and Modernization Act (MDUFMA) imposed additional premarket review and labeling requirements on reprocessors.[14] MDUFMA's most significant provisions required reprocessors to submit extensive validation data as part of their premarket notification submissions for certain reprocessed devices — data that OEMs are not required to submit on a premarket basis. In addition,

[14] Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588 (codified as amended in scattered sections of 21 U.S.C).

pursuant to MDUFMA, the premarket review requirement has been imposed on certain reprocessed devices, even though the non-reprocessed version of the device is exempt from this requirement.

The new validation requirement meant that reprocessors were obligated to submit a large amount of new data for devices that were already legally marketed, and obtain FDA clearance of these "supplemental validation data" submissions ("SVS"), or face having to remove them from the market. SterilMed, and the industry, complied with the new requirement, and FDA has completed its review of most of those submissions.

D. The Medical Device User Fee Stabilization Act of 2005

In 2005, Congress included in the Medical Device User Fee Stabilization Act (MDUFSA) a provision requiring reprocessors to place an identifying mark on their devices.[15] A device marking provision had originally been enacted as part of MDUFMA, but at that time it applied to *all* devices, not just reprocessed devices. MDUFSA modified the provision to apply *only* to reprocessors. The reprocessing industry continues to believe that the provision should have been applied to *all* device manufacturers, and believes that there was no public health rationale for applying it only to reprocessors.

IV. Safety of Reprocessed Devices

The safety record for reprocessed medical devices is outstanding. Of the tens of thousands of patient adverse event reports that FDA receives through its Medical Device Reporting (MDR) program, "only a very small percentage" concern reprocessed "single use" devices,[16] and the few problems that have occurred with reprocessed "single use" devices appear to be quite similar to the types of problems associated with new devices.[17] Indeed, in a January, 2006, letter from FDA to Congressmen Tom Davis and Henry Waxman of the House Government Reform Committee, the agency wrote that 65,325 adverse event reports had been filed with the agency since October 2003 for the malfunction or injury associated with the first use of original (*i.e.,* not reprocessed) devices labeled for "single use." The same search produced only 176 cases of apparent

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[15] Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, 119. Stat. 439 (codified as amended in 21 U.S.C. § 352(u)).

[16] GAO Report, *supra* note 3, at 15.

[17] As one example, an MDR report was submitted to FDA concerning a reprocessed EP catheter whose tip had become detached. *See* MDR Report Number 1062310-1999-00001. However, the identical incident also has been reported for new EP catheters. *See* MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. *See also* GAO Report, *supra* note 3, at 16.

malfunction or injury associated with reprocessed devices. Moreover, FDA wrote, "upon analysis of these reports, FDA determined that these adverse events are not related to the reprocessing of the SUD,"[18] and stated expressly that it "did not identify any adverse events that were actually related to the reprocessing of the SUD."[19]

Further, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) medical devices since 2004. According to the same database, no deaths have been associated with the use of reprocessed "single use" medical devices.[20]

A significant body of professional and scientific literature, much of it from peer-reviewed journals, further supports the conclusion that some single use devices can safely be reprocessed.[21] As the GAO observed when it evaluated the safety of reprocessed devices labeled for single use,

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[18] Letter from Patrick Ronan, Associate Commissioner for Legislation, Food and Drug Administration, to Chairman Tom Davis, Committee on Government Reform, House of Representative dated January 23, 2006 (the FDA reports were received between October 22, 2003 and December 13, 2005).

[19] *Id.*

[20] FDA's database of adverse events is available via the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>.

[21] Recent journal articles include the following: N. Ma, A. Petit, O. Huk, L. Yahia, and M.Tabrizian, "Safety Issue of Re-Sterilization of Polyurethane Electrophysiology Catheters: a Cytotoxicity Study," 14 *Journal of Biomaterials Science, Polymer Edition* 213 (2003); T.A. Ischinger, G. Neubauer, R.Ujlaky, H.Schatzl, and M.Bock, "Reuse of 'Single Use' Medical Devices After Quality Assured Reprocessing: Hygenic, Legal and Economic Aspects. Potential for Cost Savings in Interventional Cardiology," 92 *Z. Kardiol.* 889 (November, 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices – Regulatory Roles," 75 *AORN Journal* 98 (July 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices – Regulatory Roles," 75 *AORN Journal* 98 (July 2002); S. Mickelsen, BS, C. Mickelsen, BS, C.MacIndoe, BS, J. Jaramillo, S.Bass, MD, G. West, RN, and F. Kusumoto, MD, "Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States," 87 *The American Journal of Cardiology* 351 (February 1, 2001); C.M. Wilcox, "Methodology of Gastroenterology and Hepatology," 10 *Gastrointestinal Endoscopy Clin N Am* 379 (April 2000); R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., D.J.Patterson, M.D., J.J. Brandabur, M.D, "Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study," 49

> the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing can be carried out safely, and patient outcomes are not adversely affected by the use of reprocessed [single use devices].[22]

Because of reprocessing's exemplary record of safety, informed hospitals and physicians support the practice of reprocessing. The GAO interviewed hospital infection control practitioners, risk management executives, and patient safety experts and found that they all reported that careful reprocessing of the types of "single use" devices that are amenable to proper cleaning and sterilization does not pose a risk to patient health.[23]

Indeed, many of the most preeminent physicians in the country have publicly supported reprocessed devices as being safe and effective. For example, Dr. Bruce Lindsay, representing the American College of Cardiology (ACC) and the North American Society of Pacing and Electrophysiology (now the Heart Rhythm Society), testified before the House Commerce Committee that

> [t]here are studies, all of which have been published in peer-reviewed scientific medical journals, which have

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Gastrointestinal Endoscopy 39 (January 1999); S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E.Sumida, Ph.D., "In Vitro Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes," 94 *The American Journal of Gastroenterology* 139 (January 1999); Blomstrom, Lundqvist, "The Safety of Reusing Ablation Catheters with Temperature Control and the Need for a Validation Protocol and Guidelines for Reprocessing," 21 *Pacing Clinical Electrophysiology (PACE)* 2558 (December, 1998); M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," 32 *Journal of the American College of Cardiology* 1384 (November 1, 1998).

[22] GAO Report, s*upra* note 2, at 13 (internal citations omitted). The report went on, "For example, several studies have documented the safe reprocessing and reuse of EP [electrophysiology] catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers that reused EP catheters and centers that used each catheter only once. A later study of 69 EP catheters used in 336 procedures concluded that carefully reprocessing one model of single use catheter up to 5 times posed no increase in health risks. Similarly, some evaluations of the reprocessing of single use endoscopic instruments published in peer-reviewed scientific journals found that those [single use devices] could be reused at least several times without increasing patient risk."

[23] GAO Report, s*upra* note 2, at 14.

> evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased.[24]

Likewise, at a Senate Hearing of the Health, Education, Labor and Pensions Committee, Dr. John Clough, representing the American Hospital Association (AHA), testified that

> [m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled "for single use." The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled "for single use."[25]

In a June 23, 1999 letter to the late Senator Paul Wellstone (D-MN), Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic, discussed the Clinic's 20-year experience with reprocessed electrophysiology catheters and said:

> Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.[26]

In 2002, the Cardiac Electrophysiology Coordinator at Johns Hopkins Hospital, Carol Tunin, Ph.D., wrote of similar experiences with reprocessed catheters. In a memorandum to Rep. John Dingell (D-MI), Dr. Tunin stated that

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[24] Testimony of Bruce Lindsay, M.D., F.A.C.C., Associate Professor of Medicine, Director, Clinical EP Laboratory at Washington University School of Medicine, St. Louis, Missouri on behalf of the ACC and the North American Society of Pacing and Electrophysiology, before the House Commerce Comm., Subcommittee on Oversight and Investigations 5 (Feb. 10, 2000).

[25] Testimony of John Clough, M.D., Chair of Health Affairs, Cleveland Clinic Foundation, Cleveland, Ohio, on behalf of the AHA to the Senate Comm. on Health, Education, Labor and Pensions 3-4 (June 27, 2000).

[26] Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999).

> [t]he *entire* clinical staff of electrophysiology physicians at Johns Hopkins prefer to resterilize catheters. Ablation catheters that deliver therapy are steerable. They can be curved into multiple angles and are used to both determine the site within the heart that is the culprit of some arrhythmias and also to deliver therapy to that location. Every catheter is a bit different no matter what the brand or lot number and consistently perform with their own "character." Some even develop a slight twist or second angle that helps steer the tip onto the muscle tissue, which gives an advantage in trying to locate the source of the arrhythmia. Before resterilization was policed so tightly and the number of reuses was pared down so low, some "misshapen" catheters became favorites in trying to get into the exact position in the heart muscle.[27]

Hospitals take great comfort in the rigorous safety standards adhered to by third-party reprocessors. Indeed, SterilMed tests or inspects every reprocessed device before it is sent to a hospital, and we understand this to be the practice of the industry as a whole. This is in contrast to OEMs, who we understand typically test only a small sampling of devices. The result is that some hospitals say they prefer using reprocessed devices over original devices, because they know each reprocessed device has been individually scrutinized.

America's finest medical facilities use reprocessed medical devices, including 13 of the 14 institutions ranked by *U.S. News & World Report* in 2006 as the nation's "Honor Roll" hospitals.[28] These institutions include Massachusetts General Hospital,

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[27] Memorandum from Carol Tunin Ph.D. to Rep. John Dingell (July 12, 2002) (emphasis added). Dr. Tunin also highlighted another clinical advantage of reprocessing: because of the reduced cost of reprocessed catheters, physicians are comfortable that the cost will not be excessive if they try another tool (catheter) to see if it is more compatible with a patient's particular anatomy. Dr. Tunin noted that when pricing became a large factor at Johns Hopkins (due to restrictions on the reuse of catheters), the hospital's staff began to "limit the number of tools they will try and relentlessly persevere with one or two catheters. This often greatly extends the time on the procedure table and increases the frustration level for difficult cases."

[28] According to *U.S. News*, only the top three percent of 5,189 hospitals, 176 in all, are ranked in "one or more of the 16 specialties in this year's 'America's Best Hospitals.' And of those, just 14 qualified for the Honor Roll by ranking at or near the top in at least six specialties—a demonstration of broad expertise." The *U.S. News &World Report*'s hospital ranking can be found on the Internet at http://www.usnews.com/usnews/health/best-hospitals/tophosp.htm.

Brigham and Women's Hospital, the Mayo Clinic, the Cleveland Clinic, and Johns Hopkins University. Additionally, reprocessors serve all ten hospitals considered by *U.S. News & World Report* to be the top ten heart and heart surgery hospitals in the nation, and at least nine of the top ten orthopedic hospitals nationwide.[29]

Reprocessors also serve at least 87 percent of America's top hospitals, as listed by the 12th edition of the Solucient 100 Top Hospitals®: National Benchmarks for Success.[30] Solucient's annual list recognizes U.S. hospitals that demonstrate superior clinical, operational, and financial performance. The primary goal of the Solucient program is to use objective criteria to identify hospitals that provide the best care in the nation, and to make public the benchmark that has been set for hospital performance each year. Based on Solucient's study, reprocessors serve all of the top 25 "teaching hospitals"; at least 14 of the 15 best "major teaching hospitals"; all of the top 20 "large community hospitals"; and at least 17 of the top 20 "medium community hospitals." Overall, the major reprocessors serve 87 of Solucient's 100 Top Hospitals listed for 2004.

In short, America's finest and most respected institutions use reprocessed medical devices. It simply makes no sense to argue, as some have done and continue to do, that these institutions would put their patients at risk in order to save money. To the contrary, these facilities use reprocessed devices because they have studied the issue thoroughly and have determined that reprocessing is both safe and cost-effective.

V. Conclusion

Across the country, hospitals are facing enormous and urgent cost-containment pressures. Hospitals that cannot contain their costs are closing their doors or eliminating services, leaving too many people unserved or underserved. Reprocessing is not single-handedly going to resolve any hospital's financial pressures, but it is part of the answer. As described above, hospitals realize substantial reprocessing-related savings because the cost of a safe and effective reprocessed device is, on average, half of the cost of a new device. In addition, hospitals realize savings from reprocessing because their waste hauling and handling costs are significantly reduced. The 2000 GAO study mentioned above found that hospitals that use reprocessed devices save $200,000 to $1 million annually. To put that figure in context, for a hospital operating on a 2% profit margin, saving $200,000 is equivalent to bringing in $10 million in new revenue. The substantial savings that a hospital realizes from reprocessing can be put into hiring additional nursing staff, purchasing new capital equipment, and other patient care improvements.

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[29] *Id.*

[30] The Solucient study was released February 28, 2005 and is available at http://www.100tophospitals.com/.

Reprocessing also exerts competitive pressure on the marketplace, keeping the price of original equipment down. Biopsy forceps, for example, previously cost hospitals approximately $49 per device, but after hospitals began having them reprocessed, the price of the original devices dropped to about $15. These numbers help to clarify why the makers of biopsy forceps and other "single use devices" are so eager to persuade the world that — despite all evidence to the contrary — reprocessing is not safe. The explanation lies in their bottom line: if they are successful in eliminating reprocessing, they will be able to raise the price of those forceps to pre-reprocessing levels.

As described above, reprocessing not only makes economic sense for hospitals, it is also good for the environment. The reprocessing industry helped hospitals divert over 4,000 tons of medical waste from the waste stream in 2005 alone. Reprocessing can play a significant role in meeting the goals of the U.S. Environmental Protection Agency for reducing the health care sector's total waste volume.[31]

In short, reprocessing plays a vital role in our health care system because it is one of the few ways that hospitals can achieve substantial cost savings while maintaining the absolute highest standard of patient care. SterilMed respectfully urges the Congress to refrain from imposing additional regulation on this industry. Such regulation is unnecessary and would do nothing to enhance patient safety or improve patient outcomes. Moreover, to the extent it would limit the ability of hospitals to use reprocessed devices, such additional regulation would do a disservice to America's hospitals and patients.

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[31] *See* Memorandum of Understanding Between AHA and the U.S. Environmental Protection Agency setting forth goals to reduce the impact of health care facilities on the environment.

EXHIBIT A

Examples of OEM Legislative and Regulatory Efforts Aimed at Restricting and/or Eliminating the Third-Party Reprocessing Industry

- In the late 1990's, two device manufacturer trade associations petitioned FDA to regulate reprocessing more stringently or ban it on the grounds that it posed a public health risk. FDA denied both these petitions, stating, among other things, that the agency "has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes."[1] The agency also declared that "there is no clear evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury'" and said that it "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[2]

- In March, 2001, another device manufacturer trade association filed a Citizen Petition with FDA, claiming that reprocessed medical devices are misbranded because, among other things, reprocessors do not always remove OEM trademarks from reprocessed devices.[3] The agency denied the petition in September 2001.[4]

- There has also been significant activity at the state level. In the late 1990's, anti-reprocessing legislation was introduced, but did not ultimately succeed, in Illinois, California, and Maryland.

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[1] Letter from D. Bruce Burlington, M.D., Director CDRH, FDA, to Nancy Singer, Esq., HIMA (now AdvaMed) 2 (July 15, 1998).

[2] Letter from David W. Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry R. Pilot, Esq., Counsel to Medical Device Manufacturers Association (MDMA) 1-2 (Oct. 6, 1999). On October 21, 1999, MDMA petitioned FDA for reconsideration of its decision to deny MDMA's request for a ban on the reprocessing of "single use" devices. *See* Letter from Larry R. Pilot, Esq., to FDA (Oct. 21, 1999). FDA denied MDMA's petition for reconsideration on February 9, 2001. *See* letter from David W. Feigal, Jr., M.D., M.P.H., to Larry R. Pilot, Esq. (Feb. 2, 2001).

[3] Citizen Petition from Thomas Scarlett, Hyman, Phelps and McNamara, P.C., Counsel, Association of Disposable Device Manufacturers, to FDA (March 22, 2001).

[4] Letter from Linda S. Kahan, Deputy Director, CDRH, FDA, to Thomas Scarlett, Hyman, Phelps and McNamara, Counsel to ADDM (Sept. 17, 2001).

- At the urging of OEMs, Utah enacted legislation that requires reprocessors of critical single use medical devices to assume all liability associated with the original manufacturing of the device.[5]

- Legislation similar to that proposed in Utah, but containing additional, more burdensome requirements was considered (but failed) this year in Massachusetts, Rhode Island and Virginia. OEMs are currently promoting legislation in New Jersey that would also severely burden hospital use of reprocessed devices.

[5] Medical Device Notification and Liability, S.B. 110 (codified as amended at 78-11-28, Utah Code Annotated 1953) (2005).